REMARKS

Status of Claims

Claims 1-18, 26-31, 33, and 36-38 are canceled. Claims 19-25, 32, and 34-35 are pending.

Claims 36-38 are canceled in response to withdrawal by the Examiner as not reading on the elected invention.

Claim 32 is amended to specify that the additional drug for combination therapy is a drug for combination cancer therapy. Support for the amendment can be found in the specification as filed, including pages 6 and 7.

Claim 34 is amended to include the term prodrug and an optional additional drug for combination therapy. Support for the amendment can be found in claims 19 and 32.

No new matter is added.

Substitute Specification

Applicants submit herewith a substitute specification to correct numerous typographical errors in the specification as filed. The changes are made to be consistent with typographical corrections made in the parent application. In addition, a statement regarding government funding is added. Also, the first paragraph is amended in response to a communication from the Office of Initial Patent Examination directing Applicant to update the priority claim. No new matter is entered.

Petition for Priority Claim

Under separate cover, a *Petition for Priority Claim Under 37 C.F.R § 1.78(a)(6)* is being submitted to the Office of Petitions. The delay in requesting priority was unintentional.

Information Disclosure Statement

Applicants previously submitted evidence that the Palameta reference was properly submitted to the USPTO. The Office Action does not disagree, but indicates that a copy of the Palameta reference is not available in the parent file. For the convenience of the Examiner, a duplicate copy of Palameta is attached. Applicants request consideration of the reference, as shown by initialing and returning a copy of the Form 1449 previously submitted on Feb. 18, 2004.

Rejections Under 35 USC 112, 1st paragraph- Written Description

Pending claims 19-25, 32, and 34-35 are rejected under 35 USC 112, 1st paragraph. To clarify, claims 34-35 did not previously contain the term "prodrug" or the phrase "additional drug" and would appear to have been improperly grouped with the rejected claims, but by way of amendment, claim 34 now includes the term "prodrug" and an optional "additional drug for combination cancer therapy" and is now properly grouped with the remaining claims.

With respect to claims 32 and 34-35, Applicants traverse the rejection and respectfully request withdrawal of the rejection as the claims are amended to specify that the additional drug is an additional drug for combination cancer therapy. The Office Action of August 19, 2005 states that "The specification discloses (pages 6-7) that the intent is only to form compositions for the treatment of cancer" (Office Action, page 3). Applicants disagree with the word "only", but at least one intent of the invention is to form compositions for the treatment of cancer, and numerous examples are provided for such compositions in the listing of additional drugs provided on pages 6-7 of the specification. Specifically, the specification on pages 6-7 discloses that the identity of the other drug is not particularly limited, and suitable candidates include: a)

drugs with antimitotic effects, especially those which target cytoskeletal elements, including microtubule modulators such as taxane drugs (such as taxol, paclitaxel, taxotere, docetaxel), podophylotoxins or vinca alkaloids (vincristine, vinblastine) [page 6, lines 18-21]; b) antimetabolite drugs such as 5-fluorouracil, cytarabine, gemcitabine, purine analogues such as pentostatin, methotrexate) [page 6, lines 22-23]; c) alkylating agents such as nitrogen mustards (such as cyclophosphamide or ifosphamide) [page 6, lines 24-25]; d) drugs which target DNA such as the antracycline drugs adriamycin, doxorubicin, pharmorubicin or epirubicin [page 6, lines 26-27]; e) drugs which target topoisomerases such as etoposide [page 6, line 28]; f) hormones and hormone agonists or antagonists such as estrogens, antiestrogens (tamoxifen and related compounds) and androgens, flutamide, leuprorelin, goserelin, cyprotrone or octreotide [page 6, line 29 through page 7, line 1]; g) drugs which target signal transduction in tumour cells including antibody derivatives such as herceptin [page 7, lines 2-3]; h) alkylating drugs such as platinum drugs (cis-platin, carboplatin, oxaliplatin, paraplatin) or nitrosoureas [page 7, lines 4-5]; i) drugs potentially affecting metastasis of tumours such as matrix metalloproteinase inhibitors [page 7, lines 6-7]; j) gene therapy and antisense agents [page 7, line 8]; k) antibody therapeutics [page 7, line 9]; and l) other bioactive compounds of marine origin, notably the ecteinascidins such as ET-743, or the didemnins such as aplidine [page 7, lines 10-11].

In view of the disclosure of several classes of drugs and specific examples of drugs which are suitable candidates for inclusion in the claimed pharmaceutical composition and methods, the requirement for written description according to 35 USC § 112, 1st paragraph is met for an additional drug for combination cancer therapy.

With respect to claims 19 and 34, Applicants traverse the rejection and request withdrawal of the rejection based on the term "prodrug". The Office Action states that "in a lecture at the PTO in 2005 (cited for evidentiary purposes) Dr. Scott Hecker emphasized that it is well-known in the art that discovering prodrugs is not easy" (Office Action, page 2).

Applicants disagree with the Examiner's characterization of Dr. Hecker's presentation before the USPTO. Dr. Hecker's presentation actually states "Discovering a new class of prodrug is extremely complex, particularly if it offers advantages over known prodrug types" (Dr. Hecker's presentation, emphasis in original, page 5). However, on the same page, Dr. Hecker specifically states "Applying a known prodrug type is a relatively straightforward process" (Dr. Hecker's presentation, emphasis in original, page 5). In addition, Dr. Hecker teaches that "Success (in varying degrees) is usually obtained" (Dr. Hecker's presentation, page 5). Dr. Hecker further states that "Once [prodrugs] have been shown to work for one drug, they typically can be applied to the same functional group in other drugs" (Dr. Hecker's presentation, page 7). Finally, Dr. Hecker particularly notes both alcohol and amine functional groups as being known locations for prodrug functionalization (Dr. Hecker's presentation, page 7), and gives examples throughout the presentation of such prodrugs. Applicants note that both amine and alcohol functionality are present in the instant compounds.

Contrary to the contention of the Office Action, Dr. Hecker's presentation supports the patentability of Applicants' claims. The suggestion that Dr. Hecker emphasized that "discovering prodrugs is not easy" is not a basis to reject the claims because Applicants' claims are supported by known functional groups which Dr. Hecker himself states are useful for making prodrugs.

The Office Action appears to be making the argument that because there may be prodrugs that have yet to be discovered at some point in the distant future, the instant application lacks

written description for a claim including the term "prodrug". However, this reasoning has been specifically rejected by the courts with respect to meeting the requirements for written description. The District Court for the District of Massachusetts stated that the "written description inquiry, therefore, focuses on a comparison between the specification and the invention referenced by the terms of the claim – not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made," (*Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d at 150 (D. Mass., 2001), aff'd *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d at 1332 (Fed. Circ., 2003)). In other words, the apparent concern expressed in the Office Action for future prodrugs that may potentially be discovered at some point in the distant future is not relevant to the examination of the instant application. Simply put, the present application cannot teach (and is not required to teach) what has not yet been discovered. On the other hand, the presentation of Dr. Hecker cited by the Examiner clearly indicates that one skilled in the art having the knowledge disclosed in the application regarding the claimed compositions and the disclosure of prodrugs in the claimed compositions would recognize that the word "prodrug" readily conveys the identity of the genus, including functionalization at hydroxy and amino groups (both present in the instant claims). Applicants therefore request withdrawal of the rejection.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4126-4012. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4126-4012.

Respectfully submitted,
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Dated: November 18, 2005 By: _____

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